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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,142	08/11/1999	HENRY C. LIN	P07-42146	3370

7590

06/06/2002

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EXAMINER
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FIELDS, IESHA-P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/06/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n No.

09/374,142

Applicant(s)

LIN ET AL.

Examiner

Ilesha P Fields

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-30 and 56-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-30 and 56-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants amendment received January 23, 2002 (Paper No. 14) has been received and entered. Claims 27, 29 and 56-57 were amended and claims 12-30 and 56-58 are pending in the instant application.

#### ***Response to Amendment***

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC § 112***

1. Claims 12-30 and 56-58 rejected under 35 U.S.C. 112, second paragraph, in recitation of "SIBO" is **withdrawn** in view of Applicants amendment to the claims.

A) Claims 12-30 and 56-58 rejected under 35 U.S.C. 112, second paragraph, in recitation of "improved" is **maintained**.

Applicants assert that the limitation of "improved" is clear based on the applicants disclosures in the specification. Applicants further assert that the specification teaches that ... "improvement in a symptom(s) is typically determined by self-reporting by the human subject, for example by VAS scoring or other questionnaire". Applicants further assert that the skilled artisan would understand the meaning of "improved".

Applicants arguments have been carefully considered but not deemed persuasive.

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As stated previously, one skilled in the art would be unable to determine the meets and bounds of such a limitation. As the applicant has indicated in the response, the specification teaches that an improvement in a symptom(s) is typically determined by self-reporting by the human subject. If the patients and questionnaires vary the improvement indicated by each patient and/or questionnaire would also vary. Without a clear definition as to what constitutes as an improvement one of skill in the art would be unable to replicate the claims.

C) Claims 12 and 27 rejected under 35 U.S.C. 112, second paragraph, in recitation "substantially simultaneously" is **withdrawn** in view of Applicants amendment to the claims.

***Claim Rejections - 35 USC § 102***

2. Claims 12-30 and 56-58 rejected under 35 U.S.C. 102 (b) as being anticipated by McCann et al. is being **maintained**.

Applicants assert that the McCann et al reference is directed to a method of treating idiopathic inflammatory bowel disease (IIBD) and the applicants invention is directed at a method of treating irritable bowel syndrome (IBS).

Applicants arguments have been carefully considered but not deemed persuasive.

The claims recites a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, **or** Chrohn's disease.

McCann et al. disclose a method of treating Crohn's disease. The Examiner agrees with the applicant that McCann et al. also discloses a method of treating idiopathic inflammatory bowel disease (IBD) however, irritable bowel syndrome (IBS) and IBD belong to a family of overlapping clinical diseases/disorders. Regarding the argument that the applicants claimed method includes the step of detection, it can be reasonably concluded that if a method of treatment is administered, the disease and/or disorder had to be detected prior to treatment. Since the specification teaches that any suitable method may be used for detection, the prior art anticipates the claimed invention.

3. Claims 12-30 and 56-58 rejected under 35 U.S.C. 102 (b) as being anticipated by Sandborn et al. is being **maintained**.

Applicants assert that the Sandborn et al. reference is directed to a method of treating Inflammatory Bowel Disease (IBD) not IBS. Applicants have also asserted that Sandborn et al. fails to describe the use of 5-aminosalicylate in the treatment of IBS.

Applicants arguments have been carefully considered but not deemed persuasive.

As stated above, the claims recite a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Crohn's disease. Sandborne et al. like McCann et al. disclose a method of treating Crohn's disease. Because IBS and IBD belong to a family of overlapping clinical diseases/disorders and because the claims recite that the invention is directed to IBS or Crohn's Disease (IBD) the prior art anticipates the

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claimed invention. Regarding the argument that Sandborn et al. fails to describe the use of 5-aminosalicylate in the treatment of IBS, Sandborn et al teaches of administering 5-aminosalicylate to patients with IBD (i.e. Crohn's Disease). Moreover, such a treatment is well known in the art.

4. Claims 12-30 and 56-58 rejected under 35 U.S.C. 102 (b) as being anticipated by Becker et al. is being **maintained**.

Applicants assert that the applicants claimed invention includes the step of detection whereas the prior art lacks this step.

Applicants arguments have been carefully considered but not deemed persuasive.

The invention is directed to a method of treatment. As stated above it can be reasonably concluded that if a method of treatment is administered, the disease and/or disorder had to be detected. This step is therefore not novel but obvious. The specification teaches that any suitable method may be used for detection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

For the above reasons, it is believed that the rejections should be sustained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ilesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ilesha Fields

June 4, 2002

  
MARK NAVARRO  
PRIMARY EXAMINER